

February 18, 2010

Danny McClure
Regional Water Quality Control Board, Central Valley Region
11020 Sun Center Drive, #200
Rancho Cordova, CA 95670-6114

RE: Comments on Draft Aquatic Life Criteria for Lambda-Cyhalothrin and Cyfluthrin Developed by the University of California at Davis

Dear Mr. McClure:

The City of Roseville (City), with assistance from Robertson-Bryan, Inc., has reviewed draft water quality criteria derivation reports for lambda-cyhalothrin and cyfluthrin prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). These draft criteria derivation reports were made available for public review through email notice received on January 21, 2010 and February 4, 2010. Comments for lambda-cyhalothrin and cyfluthrin are due to the Regional Water Board by February 21, 2010 and March 6, 2010, respectively. The following comments are provided for both criteria derivation reports in advance of the February 21, 2010 deadline.

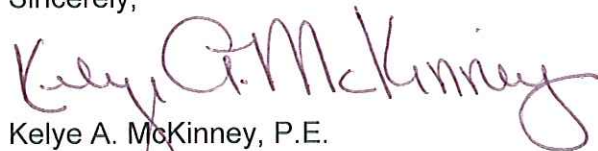
The City bases the following comments on the detailed review provided in the enclosed attachment. The City formally requests that the Regional Water Board consider these comments, and the items listed in the enclosed attachment, in light of its own review of the UCD documents and before these draft criteria are utilized for any regulatory planning or enforcement purposes.

- The City does not accept the validity of the cyfluthrin acute criterion, derived utilizing an assessment factor applied to the most sensitive freshwater species *Hyallela azteca*. Use of the assessment factor provides for unnecessary extrapolation and results in an overprotective numeric criterion. In this case, use of an assessment factor for cyfluthrin is not scientifically defensible and results in aquatic life criteria unsuitable for regulatory purposes.
- The City does not accept the validity of the cyfluthrin chronic criterion. The acute-to-chronic ratio derived is of dubious scientific applicability to the acute criterion. The use of this acute-to-chronic ratio, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin that is unsuitable for regulatory purposes.
- The City does not accept the assumption of dose additivity. Compliance with criteria should not be based on simplifying assumptions of concentration addition as the principals of concentration addition do not necessarily hold true under all possible environmental mixture scenarios. Assumptions of dose additivity are unsuitable for regulatory purposes in this case and as such allowance for dose additivity should be omitted.
- The City disagrees that pyrethroid compliance should be measured against whole water analysis. Scientific evidence points to freely dissolved pyrethroid as the bioavailable

- fraction. Compliance should be measured against that portion of a pyrethroid that is known to be toxic. The draft lambda-cyhalothrin criteria report should be revised in a manner that allows for either direct measurement of the bioavailable fraction or allow for some compensating factor accounting for particulate matter and dissolved organic matter effects.
- The recommendation in the cyfluthrin report that whole water analysis should be used in cases where total recoverable analysis achieves lower detection limits confuses the issue of analytical capability with that of toxicological relevancy. This recommendation should be removed from the cyfluthrin report and the report suitably revised to recommend that treatments or measurements of the dissolved fraction be the basis of compliance determinations.
- The capabilities of commercial laboratories in achieving low enough reporting limits is very troubling to the City. Similar to the standardization of minimum mandatory reporting limits in the State Implementation Plan (SIP), the City requests similar effort of standardization for these pesticides. Without such standardization, monitoring and compliance efforts can produce data of limited to no value, and likely at considerable economic expense to the regulated community.
- When considering the plausible future use of these draft criteria, as quantitative interpretations of existing Basin Plan narrative toxicity objectives, the City is troubled by the seeming lack of critical quality assurance review. The rounding error in the lambda-cyhalothrin report represents the second draft criteria report to include an arithmetic-related error (the first being a derivation methodology error in the bifenthrin report), and the cyfluthrin report includes an error in the description of the final criteria statement. Acute criteria should be expressed as one-hour averages and chronic criteria should be expressed as four-day averages, not the inverse. These errors unfortunately call into question the accuracy of all work pertaining to the derivation – namely the compilation, review and screening of studies for which the toxicity values are selected. The City requests a thorough outside review of all the derivation reports.

Thank you for the opportunity to comment and we look forward to your response.

Sincerely,

A handwritten signature in dark ink, appearing to read "Kelye A. McKinney". The signature is fluid and cursive, with the first name "Kelye" and last name "McKinney" clearly distinguishable.

Kelye A. McKinney, P.E.
Engineering Manager

enclosure



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TECHNICAL MEMORANDUM

Date: February 18, 2010

To: Delyn Ellison-Lloyd, Kelye McKinney, Art O'Brien (City of Roseville)

From: Michael Bryan, Ph.D., Brant Jorgenson, Ben Giudice, M.S.

Cc:

Re: Review of Draft Lambda-Cyhalothrin and Cyfluthrin Aquatic Life Criteria Reports
Developed by the University of California at Davis

1 Introduction

Robertson-Bryan, Inc (RBI) has reviewed draft water quality criteria derivation reports prepared by the University of California at Davis (UCD) while under contract to the Central Valley Regional Water Quality Control Board (Regional Water Board). Under this contract, UCD has prepared methodology and draft aquatic life criteria for a list of pesticides that the Regional Water Board has identified as posing high risks for adversely impacting water quality. The proposed methodology allows for the derivation of acute and chronic aquatic life criteria for pesticides with limited toxicity datasets. Although these criteria do not represent water quality objectives or standards at present, they may be implemented as quantitative interpretations of Basin Plan narrative toxicity objectives, and thus are of particular relevance to local agencies who manage discharges to water bodies that may be impacted by pesticides. The Regional Water Board recently adopted and submitted to the State Water Board for its approval Clean Water Act Section 303(d) listings for pyrethroid insecticide-related toxicity on Pleasant Grove Creek, South Branch Pleasant Grove Creek, and Kaseberg Creek, making the development of these draft criteria particularly relevant to the City of Roseville's (City) wastewater and storm water operations.

This technical memorandum (TM) specifically reviews criteria derivation documents that were recently released for public review by the Regional Water Board for the pyrethroid insecticides lambda-cyhalothrin and cyfluthrin. Comments for lambda-cyhalothrin and cyfluthrin are due by February 21, 2010 and March 6, 2010, respectively. Incorporated throughout these criteria derivation documents is reference to a recently developed criteria derivation methodology. Review of the criteria derivations requires review and comment on the methodology used to derive the criteria and, therefore, review of the methodology also was conducted. Due to the similarities across pyrethroid insecticides, a number of findings included in this memo are similar to those previously provided for bifenthrin. This TM summarizes RBI's findings from this review and assessment and incorporates, where appropriate, comments previously provided for bifenthrin (See RBI TM dated January 14, 2010 and submitted to the Regional Water Board on January 15, 2010).

2 Draft Criteria and Background

Draft aquatic life criteria statements from UCD for lambda-cyhalothrin and cyfluthrin are provided below. Specific comment on the criteria values and means of measuring compliance are provided in Section 3 and 4 of this memo.

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of lambda-cyhalothrin does not exceed **0.001 µg/L (1 ng/L)** more than once every three years on the average and if the one-hour average concentration does not exceed **0.001 µg/L (1 ng/L)**¹ more than once every three years on the average.” (Fojut *et. al.* 2010a)

and,

“Aquatic life in the Sacramento River and San Joaquin River basins should not be affected unacceptably if the four-day average concentration of cyfluthrin does not exceed **0.0002 µg/L (0.2 ng/L)**² more than once every three years on the average and if the one-hour average concentration does not exceed **0.00004 µg/L (0.04 ng/L)** more than once every three years on the average.” (Fojut *et. al.* 2010b)

These criteria were developed following a methodology published in September 2009. In *Methodology for Derivation of Pesticide Water Quality Criteria for the Protection of Aquatic Life, Phase II: Methodology Development and Derivation of Chlorpyrifos Criteria* (TenBrook *et al.*, 2009), a new method of criteria derivation is formalized and a step-by step procedure for deriving criteria from small toxicity datasets is provided. A new criteria derivation methodology was necessary because these limited datasets are deficient in one manner or another for use with the existing EPA methodology (EPA, 1985). The draft criteria derivation reports, which are the principal subject of this review, follow this step-by-step procedure.

The UCD methodology has been revised based on comments received from both peer review and public comment. In general, the UCD methodology developed for the task of deriving aquatic life criteria for pesticides of concern is scientifically sound. The UCD methodology is rather unique in that it lays a foundation for a regional regulatory body to develop criteria from toxicity datasets found to be incomplete by the conventional EPA method (EPA, 1985), which is most commonly used for criteria derivation purposes.

The specific manner in which this new methodology is applied in the derivation of specific aquatic life criteria is of key importance. The UCD methodology provides more than a means to derive numeric criteria; it also considers factors of bioavailability, mixture effects, and the effect of other tangential water quality parameters on pesticide toxicity (e.g., temperature and pH). Considering these other factors is complex, and caution is warranted in how assumptions are employed in developing final criteria statements and execution of those statements.

¹ This value is believed to be in error. See Section 3.6.

² The values for the four-day average concentration and the one-hour average concentration criteria are reversed. See Section 3.6.

The remainder of this review summarizes specific findings in the development and execution of these draft aquatic life criteria. Only brief effort was made to review the toxicity value screening procedure because conducting a thorough review of this aspect of the methodology was beyond the scope of this review effort. However, it should be noted that the screening of available toxicity values largely determines the criteria derivation outcome and, therefore, a thorough review of the toxicity value screening procedure by an outside party is recommended.

3 Assessment of Methodology and Draft Derivation of Lambda-Cyhalothrin and Cyfluthrin Criteria

3.1 Use of Assessment Factor Approach for Cyfluthrin

In the development of draft criteria utilizing the UCD methodology, several safety factor iterations are employed in order to compensate for informational deficiencies in limited datasets. In the case of the draft cyfluthrin criteria derivation report (Fojut *et al.*, 2010b), an acute criterion was derived by taking the single most sensitive acute result of 0.0023 µg/L and dividing it by an assessment factor of 5.1 (due to only 4 taxa being available—as per Table 3.13 in the methods), and dividing by a further factor of 2 to convert from an LC₅₀/EC₅₀ to an assumed NOEC. As required by the UCD methodology, the assessment factor approach was utilized in place of the more robust species sensitivity distribution approach because data for only four of the necessary five taxa were available. The missing taxa was an insect.

The lowest species mean acute value of 0.0023 µg/L was for *Hyallela azteca*. *H. azteca* is known to be an exceedingly sensitive freshwater species to pyrethroid exposure. In the draft criteria reports for bifenthrin, lambda-cyhalothrin, and cyfluthrin, *H. azteca* is presented as the most sensitive species when comparing species mean acute toxicity values. In Solomon *et. al.* (2001), the authors assert that variation in pyrethroid species sensitivity is similar. However, using the assessment factor approach for cyfluthrin results in an acute criterion nearly one order of magnitude less than that derived for bifenthrin and lambda-cyhalothrin. The most sensitive freshwater species, as presented in these three pyrethroid datasets are the same – *H. azteca*. Actual sensitivities in *H. azteca*, as summarized in the pyrethroid criteria reports, varies by a factor of 3.

Derivation of the draft cyfluthrin criteria illustrates some of the short-comings inherent to the assessment factor approach in the UCD methodology. When a dataset is limited by the absence of an acute toxicity value representative of a specifically required taxa, use of an assessment factor presumes the potential existence of a more sensitive species not reflected in the available data. In the case of cyfluthrin, *H. azteca* is very likely the most sensitive freshwater species, and applying an uncertainty factor of 5.1 likely overestimates species sensitivity, resulting in an overly conservative acute criterion.

Assessment factors themselves are cumbersome tools when used to derive quantitative aquatic life criteria for regulatory purposes. They act as semi-quantitative uncertainty factors in order to overcome gaps and deficiencies in a dataset. The assessment factors employed in the UCD methodology are semi-quantitative inasmuch that they are based on toxicity datasets for chlorpyrifos, DDT, toxaphene, endrin, lindane, aldrin, dieldrin, heptachlor, chlordane, and endosulfan, none of which are pyrethroid insecticides. While use of assessment factors can serve to reduce the probability

of underestimating risk in cases where data are limited, the very conservative nature of assessment factors greatly increases the probability that risk is overestimated. While criteria developed by including such uncertainty factors may serve a suitable purpose in risk assessment evaluations, they should not be used for regulatory compliance purposes. And while uncertainty factor driven criteria maintain utility in a risk assessment arena, before their use they should be evaluated against other lines of evidence that suggest they might err unnecessarily in favor of overprotection, as in this case with cyfluthrin. Context and scientific knowledge are important considerations in the use of assessment factors, and the context here suggests that the draft criteria for cyfluthrin is overprotective.

3.2 Implementation of Acute to Chronic Ratios

In cases when data from fewer than five taxa are present, the methodology requires that acute-to-chronic ratios (ACRs) be used. For lambda-cyhalothrin and cyfluthrin, ACR's were derived from pyrethroid specific datasets. However, *H. azteca* is the most sensitive species and the one that drives the acute value. There is no ACR in the datasets for this species or its taxon. Furthermore, for cyfluthrin, the concentrations at which ACRs are derived in Table 8 are ~2 orders of magnitude higher than the acute value. For these reasons, it is not clear that the ACR methodology provides a scientifically reasonable means of deriving chronic criteria, particularly in the case of cyfluthrin, for which the derived chronic criterion is 332 times lower than the most sensitive chronic value in the acceptable dataset. The use of the derived ACR, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin.

3.3 Assumed Dose-Effect Additivity

Environmental toxicologists recognize the importance of considering toxicant mixtures when evaluating and predicting toxicity to an organism. It is a held theory that toxicants of similar mode of action can act additively on an organism. Through such simplifying models of concentration addition, the effect of dose additivity can be predicted. In the lambda-cyhalothrin and cyfluthrin criteria reports, where toxic modes of action are considered the same, the reports state in similar fashion:

“Since compounds in this class have a similar mode of action, either the toxic unit or the relative potency factor approach can be used to determine compliance in cases where pyrethroid mixtures are present in environmental samples...” (Fojut *et al.*, 2010a)

Admittedly, this principal of toxicology holds well, but one must question how *similar* a toxic mode of action must be, how many mixture components there are, and at what concentration ratios for the assumption of additivity to hold true under all likely environmental scenarios. Caution is advised in applying concentration addition models in cases of compliance determination. For example, Trimble *et al.* (2009) investigated additivity in binary mixtures of Type I and Type II pyrethroids. Although concentration addition models predicted experimental results well, as would be hypothesized, in some cases so did independent action models. Furthermore, actual toxicity often deviated substantially from predicted toxicity at low toxicant concentration, well below expected LC₅₀ values (i.e., in the range of the derived acute criterion). There is enough inherent uncertainty in the use and applicability of concentration addition models, be they toxic unit or relative potency factor approaches, that pause should be taken before assessing compliance based on assumed additivity.

3.4 Bioavailability

The UCD criteria derivation methodology should be lauded for including considerations of bioavailability. In Section 9 of the draft lambda-cyhalothrin and cyfluthrin criteria reports a the propensity of pyrethroid insecticides to sorb to particulate matter, sediments, and laboratory equipment is discussed. In this discussion several studies are mentioned providing evidence that pyrethroid toxicity in the water column is associated with the dissolved fraction, and that the freely dissolved fraction is the better predictor of toxicity.

The draft criteria reports make two different recommendations on the matter of bioavailability. Similar to the recommendation contained in the previously published bifenthrin report, the lambda-cyhalothrin report recommends that compliance with the lambda-cyhalothrin criteria be determined based on the total recoverable, whole-water fraction. This recommendation is made rather arbitrarily in an effort to balance error associated in toxicity measurements reporting nominal spiked concentration with that of the error in predicting toxicity with the use of whole-water measurements. By assuming these relative errors to be equal, and thus cancelling, the authors attempt to strike a balance between the over prediction of toxicity when utilizing a total recoverable analytical measurement with the under prediction of toxicity when utilizing a nominal spike concentration in determining LC_{50} 's. There is no justification for this balance, the result of which knowingly biases a compliance measurement in favor of overprotection once again.

Conversely, the cyfluthrin report makes the recommendation that compliance determinations be based on the freely dissolved fraction which more accurately reflects scientific understanding of pyrethroid bioavailability in the environment. However, this recommendation is made with a caveat, that dissolved pyrethroid analytical measurements should only be used if analytical method detection limits meet or exceed the total recoverable analytical counterpart. The reasoning for this caveat centers around dissolved fraction analytical sensitivity concerns. Analytical sensitivity is an issue of concern regardless of analytical methodology employed, particularly with acute and chronic criteria in the part-per-trillion and sub-part-per-trillion range. Analytical detection issues aside (see Section 3.5 for more detail), if a total recoverable analytical method could give a lower reporting limit in comparison to an appropriate dissolved analytical method, the lower analytical reporting limit itself does not, by any scientific standard, make the result a more accurate measure of the truly bioavailable fraction. In light of the current scientific understanding of pyrethroid bioavailability, any total recoverable measurement unadjusted to account for the fraction that is not bioavailable represents a knowingly biased measurement and should not be used for compliance determination.

3.5 Analytical Concerns

For compliance testing purposes through National Pollutant Discharge Elimination System (NPDES) permits, EPA approved methodologies must be used. Existing analytical methods for the measurement of semi-volatile organic pollutants such as pyrethroid insecticides are limited in the capability of achieving the draft criteria values derived for lambda-cyhalothrin and cyfluthrin. Only the most diligent commercial laboratories can achieve reporting limits near the acute lambda-cyhalothrin criterion using these analytical methods and employing good laboratory practices and standard quality assurance. There is limited commercial analytical capacity in California, and at

present most laboratories could only assure reporting limits several times greater than the draft acute criteria. This limits the utility of criteria altogether, and potentially returns the regulated community to a position of providing the Regional Water Board with analytical results containing varied reporting limits. When using such criteria, maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.

3.6 Calculation Error and Error In Criteria Statements

The final chronic criterion derived for lambda-cyhalothrin appears to include a rounding error. The chronic criterion for lambda-cyhalothrin should be 0.5 ng/L.

In the cyfluthrin draft derivation report, the concluding criteria statement confuses averaging periods for acute and chronic criteria. Acute criteria should be one-hour average values and chronic criteria should be four-day average values.

4 Summary of Review Findings

Review findings are summarized as follow:

1. Overly conservative extrapolation through the use of an assessment factor (i.e., uncertainty factor) for cyfluthrin yields an acute criterion of questionable scientific validity. Context and scientific knowledge should be employed in evaluating the appropriateness of the utilized assessment factor. The assessment factor used not only was derived from a list of insecticides that does not include any pyrethroids, the assessment factor was applied to a *H. azteca* LC₅₀ value. *Hyallela azteca* is known to be exceptionally sensitive to pyrethroid exposure; indeed, *H. azteca* pyrethroid sensitivity is rarely exceeded.
2. The acute criterion for lambda-cyhalothrin is based on a species distribution approach and results in a supportable criterion compared to that derived from an assessment factor approach.
3. The ACR derived for lambda-cyhalothrin is based on a dataset that does not contain the most sensitive species *H. azteca* or its taxon. Therefore, there is no way to determine whether the derived value of the ACR is appropriate for application to the acute value. The ACR derived for cyfluthrin has the same deficiency, but also relies on a dataset in which LC₅₀s are ~2 orders of magnitude higher than the LC₅₀ to which the ACR is applied. The resulting ACR is of questionable scientific validity, and this shortcoming is compounded by the assessment factor used to derive the acute criterion, as discussed above. The use of the derived ACR, combined with the assessment factor used to derive the acute criterion, results in an overprotective chronic criterion for cyfluthrin.
4. For all derived criteria, the assumption of dose additivity between pesticides of similar mode of toxicity is assumed. Caution is advised in applying concentration addition principals to compliance measurements. Dose additivity is not settled science, and its accuracy as a model predictor is sensitive to many variable factors. Where science is not settled, compliance should not be based on simplifying assumptions.

5. The current scientific understanding regarding pesticide bioavailability should be applied to criteria compliance determinations. The freely dissolved fraction of pyrethroid insecticides, including lambda-cyhalothrin and cyfluthrin, is the fraction that is bioavailable. Compliance should be based on measurements that most accurately predict toxicity. Either compliance should be determined using analytical procedures measuring the dissolved fraction, or compliance should be determined using total recoverable methods but adjusted for pyrethroid sorption to particulate matter and dissolved organic matter.
6. Achieving commercially available analytical reporting limits below the pyrethroid criterion utilizing EPA approved methods is currently lacking or limited. Maximum matrix-specific reporting limits should be considered so as to avoid the potential of reporting false positives and errant detections.
7. The rounding error contained in chronic criterion for lambda-cyhalothrin should be corrected. The final criteria statement for cyfluthrin should accurately state acute and chronic averaging periods.

5 References

- Fojut, T.L., R.S. Tjeerdema. 2010a. *Lambda-Cyhalothrin Criteria Derivation*. Draft. Environmental Toxicology Department, University of California, Davis. Davis, CA.
- Fojut, T.L., S. Chang, R.S. Tjeerdema. 2010b. *Cyfluthrin Criteria Derivation*. Draft. Environmental Toxicology Department, University of California, Davis. Davis, CA.
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